MCO-400

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN

COMMONWEALTH PHARMACEUTICALS, LTD., and IMMUNE MODULATION MAXIMUM CORP.,

Plaintiffs,

v.

ADVANCED VIRAL RESEARCH CORP.,

Defendant.

Joseph P. Carrier (P45172)
William D. Blackman (P40549)
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Attorney for Plaintiffs

Case No. 257 3521 PAUL D. BORMAN HON. Judge CO

VERIFIED COMPLAINT FOR DECLARATORY AND OTHER RELIEF

NOW COME the Plaintiffs, COMMONWEALTH PHARMACEUTICALS, LTD. and IMMUNE MODULATION MAXIMUM, and for and as their Verified Complaint, state as follows:

Introduction

1. This action arises out of clear and egregious actions by the Defendant including false advertisement.

Subject Matter Jurisdiction

2. Jurisdiction is proper pursuant to 28 USC § 1338 as the Defendant has violated 15 USC § 52 by falsely advertising ownership of a pharmaceutical product. Jurisdiction is also proper under 28 USC § 1338 as patent ownership is in dispute. In addition, jurisdiction is proper pursuant to 28 USC §1332 as Plaintiff Commonwealth Pharmaceuticals, Ltd. is a Caymanian corporation, maintaining a place of business in Grand Cayman, Cayman Islands, British West Indies and maintains an office in Trenton, Michigan; Plaintiff Immune Modulation Maximum Corp. is a Delaware Corporation and maintains its only office in Trenton, Michigan; Defendant is a Delaware Corporation with headquarters in Yonkers, New York; and the value of the dispute exceeds \$75,000.

Parties

- 3. Plaintiff, Commonwealth Pharmaceuticals, Ltd. (hereinaster "Commonwealth"), is a Caymanian corporation, maintaining a place of business in Grand Cayman, Cayman Islands, British West Indies and maintains an office at 20925 Newman Drive, Trenton, Michigan 48183.
- 4. Plaintiff, Immune Modulation Maximum Corp. (hereinafter "IMMC"), is a Delaware Corporation and maintains its only office at 20925 Newman Drive, Trenton, Michigan.
- 5. Defendant, Advanced Viral Research Corporation (hereinaster "ADVR"), is a publicly-traded company that upon information and belief is incorporated under the laws of Delaware with its headquarters at 200 Corporate Blvd. South, Yonkers, New York 10701.

Common Allegations

- 6. Dr. Vincent Lapenta invented the antiviral pharmaceutical drug commonly known as Reticulose in the 1930s. Together with his son, B.E. Lapenta, Dr. Lapenta successfully used the drug in the treatment of many diseases.
- 7. B.E. Lapenta established Chemico Laboratories in the early 1940s to manufacture and market Reticulose.
- 8. Dr. Lapenta only disclosed relevant technology of the manufacturing process of Reticulose to

- B.E. Lapenta and together they conducted the manufacturing of the drug initially in Indianapolis and beginning around 1959 in Miami, Florida, but throughout Dr. Lapenta and B.E. Lapenta personally, and confidentially maintained all key technology and trade secrets of the manufacturing process.
- 9. Dr. Lapenta passed away in the 1950s and all rights in the confidential technology and manufacturing process transferred to his heirs including B.E. Lapenta.
- 10. From about 1960 to 1962 Chemico Laboratories granted an exclusive distributorship of Reticulose to Phillips Roxanne Pharmaceutical Inc. (hereinafter "Phillips Roxanne"); during this time period more than 1,000,000 ampules of Reticulose were sold.
- 11. In 1962, the U.S. FDA issued a series of new Drug Regulation, reclassifying Reticulose as a "New Drug" whereby requiring expensive re-filing, documentation and testing before Reticulose could again be sold; because Phillips Roxanne did not want to incur the costs associated with new testing, etc. they released Chemico from the exclusive distribution contract and returned the distribution of the product to Chemico and the Lapentas. Although Reticulose was no longer FDA approved, there remained a large stock of the product stored in sealed glass ampules.
- 12. B.E. Lapenta subsequently in approximately 1965 entered into an agreement wherein

 Reticulose would be manufactured under Lapenta's supervision and control since he still

 remained the only person with the confidential knowledge of how to manufacture Reticulose, in

 manufacturing facilities to be built by Key Pharmaceuticals in Freeport, Bahamas; Key would

- only have distribution rights to the drug and would be responsible for all costs and efforts to obtain FDA approval of Reticulose.
- 13. By 1969, the manufacturing facility was built, but Key came to the decision that the expense of satisfying the costs and requests of the FDA to obtain approval of Reticulose was too great to pursue and withdrew the application for Reticulose from the FDA.
- 14. In about 1972, Key merged with Transmedix and the new merged company sold any distributorship rights it may have still had in Reticulose via the agreement with Chemico, including Key's manufacturing facilities and any stock of glass sealed ampules to Cepher Chen Yan Sun and his company, Grace Limited Partnership of Singapore as Mr. Chen believed he could successfully sell Reticulose in China.
- 15. In 1972, Lapenta and Chemico filed suit against Key in the Circuit Court of the Eleventh Judicial Circuit in Dade County, Florida for amongst other things, breach of the agreement between the entities, although the final result of the lawsuit is uncertain, it was dismissed in about 1976.
- 16. In 1976, B.E. Lapenta passed away and his confidential information on the manufacturing process of Reticulose transferred to his heirs, who subsequently formed Chemico II and maintained confidentiality of the information.
- 17. Cepher Chen Yan Sun fell into great legal and financial difficulties and the Hong Kong court put Mr. Chen into Bankruptcy, and all the Reticulose assets were placed into the hands of a Hong Kong court receiver.

- 18. In or about 1984, Bernard Friedland, former lab technician at Key, and his partner William Bregman, learned of Mr. Chen's bankruptcy and purchased whatever rights (if any) and stock of Reticulose were passed to the Hong Kong court receiver, and subsequently in 1984, an American Company, the Defendant Advanced Viral Research Corp., was formed to exploit whatever rights Friedland et al. may have had in Reticulose.
- 19. Advanced Viral Research Corp ("ADVR") filed for IPO in 1986, which required ADVR to disclose the history of Reticulose and whatever rights it has therein; and although ADVR alleges to have all ownership rights to Reticulose, including the confidential manufacturing know-how (directly contrary to the position of the Lapenta heirs), ADVR has never substantiated this claim with any written documentation to prove such broad/exclusive ownership rights in Reticulose.
- 20. The written agreement entitled "Contract with Distributor" was entered into by Commonwealth and ADVR on October 25, 1994 (the "1994 Agreement"), which purported to grant Plaintiff Commonwealth the exclusive rights to distribute the antiviral pharmaceutical product, known by the name "Reticulose" within the territory and country Channel Islands, Isle of Man, British West Indies, Jamaica, Haiti, Bermuda, and Belize. Exhibit A ¶1. Commonwealth entered into the 1994 Agreement based on ADVR's representations of broad/exclusive ownership rights in Reticulose.
- 21. On November 2, 1995, Commonwealth, again relying on ADVR's representations of broad/exclusive ownership rights, entered into another exclusive distribution agreement with ADVR, (the "1995 Agreement"), which purported to grant Plaintiff Commonwealth the rights to distribute Reticulose within the territory and country of Saudi Arabia. Exhibit B ¶ 1.
- 22. The 1995 Agreement provides that "[t]his agreement supercedes all previous agreements

- between the parties" and therefore is the only binding agreement between Commonwealth and ADVR, as its terms supercede those in the 1994 Agreement. Exhibit B ¶6.
- 23. Commonwealth detrimentally relied on ADVR's assertions made in the 1994 and 1995 Agreements, and spent a great deal of time, money and effort attempting to attain the licenses necessary to sell Reticulose in the countries specified in the Agreements, which were ultimately completely frustrated (and was unable to sell ANY Reticulose) because ADVR would not and could not obtain the necessary Free Sale Certificate, and despite ADVR's assurances that it would provide the necessary Free Sale Certificate.
- 24. In 1996, IMMC became aware that ADVR did not own the broad/exclusive rights in Reticulose which they openly claimed to own, but that instead the Lapenta heirs actually owned such broad/exclusive rights.
- 25. In an agreement titled "Technology Purchase Agreement" dated May 16, 1996, the Lapenta family, through their corporation "Chemico II," granted IMMC all rights to the drug Reticulose. See Exhibit C.
- 26. The 1995 Agreement between Commonwealth and ADVR provides in ¶22 (emphasis added):

All laboratory or clinical studies initiated by the Distributor for which RETICULOSE is provided must first be approved by the Company. The results of all studies, all research data and documentation and any research publications resulting from studies initiated by Distributor or any of his agents will belong to Company, and will be made use of at Company's discretion, and such studies are only permitted as part of this exclusive agreement. Said studies, research data, documentation, or publications to be provided to Company in the English language, in addition to the language of origin.

27. United States Patent 5,849,196 issued on December 15, 1998 and assigned to IMMC, of which Charles Miller owns an interest, is based on in vitro research conducted with

Reticulose by Bonawentura Kochel in Poland using stock of Reticulose manufactured in the 1960s and provided by Barney Donner and Plata Pharmaceuticals, Inc. who had previously purchased the stock from ADVR. Exhibit D. Dr. Kochel assigned all his rights title and interest in the invention encompassed by said patent to IMMC. Exhibit E.

- 28. ADVR has recently filed a Complaint against Commonwealth, IMMC and Miller in the Supreme Court of the State of New York, County of Westchester in which ADVR seeks to have United States Patent 5,849,196 assigned from IMMC to ADVR based on ¶22 of the 1995 Agreement; although, IMMC is seeking to have such lawsuit dismissed for multiple reasons, including primarily lack of personal jurisdiction over all named Defendants.
- 29. In any event, ¶22 of the 1995 Agreement was not violated by Commonwealth or any other person/entity as ADVR did not provide gratis the Reticulose for the research.
- 30. In the January 13, 1999 S1 filing by ADVR with the U.S. Security and Exchange Commission, in the section entitled "Potential Claim for Royalties", ADVR admitted that it does not have any documented proof of its alleged broad/exclusive ownership rights in Reticulose, instead in the filing, ADVR states that there was an "Alleged Contract" conveying such rights to Key in ADVR's alleged chain of title to the rights.

Count I

Declaratory Judgment to Establish Ownership of Confidential Technology Pertaining to Manufacture, etc. of Reticulose

- 31. Paragraphs 1 through 30 above are incorporated herein by reference as though fully set forth herein.
- 32. This is a claim for a declaration that IMMC is the exclusive owner of the broad/exclusive rights in Reticulose, including the confidential and proprietary information on manufacturing Reticulose, based on the May 1996 Technology Purchase Agreement between IMMC and Chemico II, as well as the lack of any documentation establishing any such ownership rights in ADVR. This Court has jurisdiction over the subject matter of this claim pursuant to 28 USC §§ 2201, 2202.
- 33. Defendant ADVR has continuously asserted publicly since at least 1986 that it is exclusive owner of the broad/exclusive rights in Reticulose, including the confidential and proprietary information on manufacturing Reticulose, and that ADVR has somehow (in its alleged chain of title) acquired such rights from Dr. Vincent Lapenta and his heirs.
- 34. ADVR's statements are contradicted by the statements and actions of the heirs of Dr. Lapenta, including the May 1996 Technology Purchase Agreement between IMMC and Chemico II.
- 35. An actual controversy exists between the parties.

Count II

Declaratory Judgement To Establish Exclusive Ownership of US Patent 5,849,196 by IMMC

- 36. Paragraphs 1 through 35 above are incorporated herein by reference as though fully set forth herein.
- 37. This is a claim for declaration that IMMC is the exclusive owner of US Patent 5,849,196 based on assignment of such patent to IMMC by the inventor, Bonawentura Kochel. This Court has jurisdiction over the subject matter of this claim pursuant to 28 USC §§ 1331, 1338, 2201 and 2202.
- 38. ADVR has asserted ownership rights of US Patent 5,849,196 in the lawsuit filed in New York Supreme Court (see § 27).
- 39. ADVR has asserted to others that IMMC is not the rightful owner of US Patent 5,849,196.
- 40. ADVR's statements are inconsistent with both the facts involved in IMMC's acquiring the ownership rights, and with ¶22 of the 1995 Agreement.
- 41. An actual controversy exists between the parties.

Count III

Violations of the Lanham Act

- 42. Paragraphs 1 through 41 above are incorporated herein by reference as though fully set forth herein.
- 43. ADVR's representation that it, not IMMC, owns the exclusive/broad rights to Reticulose

- constitutes a false designation of origin, false or misleading description of fact, or false or misleading representation of fact in violation of §43(a) of the Lanham Act (15 U.S.C. § 1125(a)(1)(A),(B)).
- 44. ADVR has falsely claimed to own broad/exclusive rights to the drug Reticulose and the trademark to such name, in violation of 1 §43(a) of the Lanham Act (5 U.S.C. §1125).
- 45. IMMC, not ADVR, owns the broad/exclusive rights to the drug Reticulose as well as ownership of the trademark to such name based on the Technology Transfer Agreement between IMMC and Chemico II commercial activities using same.
- 46. Plaintiffs are harmed by Defendant's acts.
- 47. Defendant's acts were willful and deliberate.

Count IV

Misrepresentation

- 48. Plaintiff incorporates paragraphs 1 through 47 as if fully set forth herein.
- 49. ADVR falsely represented to Commonwealth at the time the 1994 and 1995 Agreements were signed and throughout their relationship that it possessed the broad/exclusive ownership rights in Reticulose necessary to enter into the Agreements and to allow Commonwealth to benefit from the alleged granted rights.
- 50. ADVR also represented to third-parties that it owned the broad/exclusive ownership rights in Reticulose.

- 51. Commonwealth did not know of the falsity of ADVR's representations concerning ADVR's rights in Reticulose and relied on those representations to its detriment.
- 52. Such representation were material and false and ADVR knew such representation were false or made them recklessly without knowledge of their truth as a positive assertion.
- 53. ADVR made such representation with the intent to mislead Commonwealth and its investors into relying on such representations.
- 54. As a direct and proximate result of ADVR's misrepresentations to Commonwealth and others,

 Commonwealth has incurred and continues to incur substantial costs, expenses and damages

 with the exact amount to be determined at trial.

Count Y

Temporary Restraining Order, Preliminary and Permanent Injunction

- 55. Plaintiffs incorporate paragraphs 1 through 54 as if fully set forth herein.
- 56. Plaintiffs are substantially likely to succeed on the merits because ADVR (1) falsely represented that it owned the broad/exclusive rights to Reticulose, (2) openly admitted it did not have the necessary documentation to prove such broad/exclusive rights whereas Plaintiffs have documented proof of ownership, (3) knowingly entered into agreements granting rights it did not have the power to grant and (4) knowingly entered into agreements from which it knew Commonwealth could not benefit.
- 57. If ADVR is allowed to continue to assert broad/exclusive ownership of Reticulose and to interfere with the Plaintiffs' business, the Plaintiffs will suffer irreparable harm in the

- form of lost profits and their ability to use Reticulose and fully exploit their own rights.
- 58. Furthermore, damage to the reputation established by the Plaintiff Corporations is irreparable.
- 59. The harm to the Plaintiffs outweighs any impact on the Defendant if a temporary restraining order, preliminary injunction and permanent injunction is not entered and ADVR is permitted to continue soliciting investors, asserting broad/exclusive ownership of Reticulose to its investors.
- 60. The public interest will be served if a temporary restraining order, preliminary injunction and permanent injunction is issued because of ADVR's wrongful assertion of broad/exclusive ownership of Reticulose irreparably harms the public who is purchasing ADVR's publicly-traded stock based on the falsely alleged ownership.
- 61. The actions of ADVR to market Reticulose and solicit investors are continuing, including current efforts to sell millions of shares of ADVR stock currently owned by ADVR insiders.

Count VI

Unjust Enrichment

- 62. Paragraphs 1 through 61 above are incorporated herein by reference as though fully set forth herein.
- 63. ADVR received tremendous benefits from Commonwealth from Commonwealth's

- activities based on the Distribution Agreements.
- 64. ADVR has received and is continuing to receive tremendous financial support from investors who have purchased stocks based on ADVR's false representations.
- 65. ADVR is unconscionably and inequitably asserting broad/exclusive ownership rights of Reticulose, for which IMMC actually owns all right, title and interest.
- 66. It would be unconscionable and inequitable for Defendants to retain the benefits it has received from its false representations to Commonwealth and third-parties.
- 67. An actual controversy exists between the parties and the Plaintiffs are entitled to the broad/exclusive rights to Reticulose, exclusive ownership of U.S. Patent 5,849,196, and a monetary amount to be determined at trial.

Count VII

Demand for Arbitration

- 68. Paragraphs 1 through 67 above are incorporated herein by reference as though fully set forth herein.
- 69. Although Plaintiffs in Count II ask the Court to declare IMMC as the exclusive owner of U.S. Patent 5,849,196, in the alternative, Plaintiffs ask the Court makes the instant demand for arbitration relative to said Count.
- 70. The 1995 Agreement in \$16 provides:

In the event of any dispute between the parties, regarding the interpretation or the application of this agreement, recourse will be handled by an arbitration panel of three arbitrators, one arbitrator to be chosen by each party, and the third arbitrator to be appointed by the two arbitrators. The decision of the arbitrators is final. It is understood, however, that this is a

general form of agreement, designed for use in the United States of America, and in countries wherever Company may desire to sell RETICULOSE and that any provision herein which in anyway contravenes the laws of any country or jurisdiction, shall be deemed not to be a part of this agreement therein.

- 71. All disputes arising from or pertaining to the 1995 Agreement should be resolved through arbitration pursuant to \$\Pi\$16 of the Agreement.
- 72. Defendant ADVR has disregarded ¶16, the arbitration clause of the 1995

 Agreement in filing the Complaint in the Supreme Court of the State of New

 York in the County of Westchester as mentioned above.
- 73. Prior to filing said Complaint, ADVR did not attempt to initiate arbitration with Plaintiff Commonwealth and/or Plaintiff IMMC, as required by ¶16 of the 1995 Agreement, therefore arbitration should be compelled pursuant to Section 4 of the Federal Arbitration Act (9 U.S.C. §4).

WHEREFORE, Plaintiffs ask the Court to:

- A. Declare IMMC as the exclusive owner of the broad/exclusive rights in Reticulose, including the confidential and proprietary know-how involved in manufacture of the composition;
- B. Declare IMMC as the exclusive owner of U.S. Patent 5,849,196 and any subsequent related patents that may be issued, or in the alternative, demand the parties to submit to arbitration administered by the American Arbitration Association under its

- Commercial Arbitration Rules for the disputes arising from or pertaining to the 1995 Agreement;
- C. Enjoin Defendant and its Agents from further attempts to use, market or assert any claims of ownership over any broad/exclusive rights in Reticulose, including the confidential and proprietary know-how involved in manufacture of the composition;
- D. To enjoin the Defendant and its Agents from further stating to anyone that IMMC is the owner of broad/exclusive rights in Reticulose or from otherwise interfering with Plaintiffs' exercise and exploitation of their rights;
- E. That Defendant's acts are adjudicated to be willful and deliberate;
- F. The enjoin the Defendant and its Agents from any future use, publication and disclosure of Plaintiffs' proprietary and confidential information relating to Reticulose;
- G. Demand Defendant to assign any Reticulose-related trademarks over to IMMC;
- H. That this Court either impound or order Defendant to disgorge and return to Plaintiffs all material containing Plaintiffs' confidential information and data in Defendant's possession, custody or control, including all data, customer data bases or client information;
- I. That Defendant pay to Plaintiffs (1) Defendants' profits, (2) any damages sustained by the Plaintiff, and (3) the costs of this action as provided in 15 U.S.C § 1117;
- J. That this Court increase damages and profits sustained in violation of the Lanham Act up to three times, pursuant to U.S.C. § 1117;

K. That this case be declared exceptional and that the Court award Plaintiffs their

reasonable attorney fees pursuant to U.S.C. § 1117;

L. To order by way of equitable relief, a full and complete accounting of any of

Defendant's benefits Defendant may have received as a result of its misrepresentation of

broad/exclusive ownership in Reticulose;

M. To award Plaintiffs their damages, including exemplary damages, interest, costs and

attorney fees pursuant to Counts III and VI; and

N. To award Plaintiff any other relief previously sought in this Complaint and to impose

other relief that this Court finds just and proper.

Plaintiffs, Commonwealth Pharmaceutical Ltd. And Immune Modulation Maximum Corp.,

demand a trial by jury.

The Statements Above Are True And Correct To The Best Of My Knowledge, Information, and Belief.

Charles F. Miller

President of Commonwealth

Charles E. Miller,

President of IMMC

Respectfully submitted,

CARRIER, BLACKMAN &

ASSOCIATES, P.C.

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Dated: August 2, 2000

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN

SEE CASE FILE FOR ADDITIONAL DOCUMENTS OR PAGES THAT WERE NOT SCANNED